



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/726,963

12/03/2003

David Ernest Hartley

PA-5351-RFB

4386

9896 7590 03/03/2009

COOK GROUP PATENT OFFICE

P.O. BOX 2269

BLOOMINGTON, IN 47402

EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,963	Applicant(s) HARTLEY ET AL.	
	Examiner Ryan J. Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,9,17,18 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9,17,18 and 20-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 2, 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox et al. (5,824,040).** Cox et al. disclose a prosthesis comprising a plurality of self-expanding stents (114, see column 13, lines 41-43) linked together by flexible links (130, see figure 7E) that comprise threads (see column 14, lines 33-38). A biocompatible graft cover (112) covers the inner surface of the stents, thereby defining the “covered stent portion”. The “uncovered stent portion” is considered the outer surface of the stents. Examiner notes that the claims in no way require the stents of the covered and uncovered portions to be discrete stents. Claim 1 also fails to make clear the manner in which the stents in the covered stent portion are covered (i.e. whether the inner or outer surface, or both, is that which is covered by the graft). Further, the term “portion” as used in the claims is extremely broad and can not be limited to configurations in which each “portion” defines a distinct series of stents. In light in the failure of claim 1 to set forth meaningful structure in this regard, the claims are given the broadest reasonable interpretation as set forth above.

Claim Rejections - 35 USC § 103

Art Unit: 3731

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (2002/0120327).** Cox et al. do not disclose the knot holding the threads to the stents. However, Examiner asserts the use of a specific knot would have been obvious to one of ordinary skill in the art at the time the invention was made and that by using any of the claimed knots, no unexpected results would be produced.

5. **Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (2002/0120327) in view of McNamara et al. (6,004,347).** Cox et al. do not disclose the graft on the outside of the stent, and barbs extending from the stent through the graft. Attention is drawn to McNamara et al., who teach a graft disposed on the outside of a stent with a barb penetrating through the graft (see figures 10 and 11) to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have disposed the graft of Cox et al. on the outside of the stents and included barbs on the stents in the manner taught by McNamara et al. to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed.

6. **Claims 17, 18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (2002/0120327) in view of Brown et al. (5,769,887).**

Art Unit: 3731

Cox et al. do not disclose at least three stents within the cover and a plurality of stents extending from the cover. Attention is drawn to Brown et al., who teaches a graft may cover the outside of only one end of the series of stents (see figure 8) prevent having to cover the entire stent (thereby minimizing the cross-sectional area of the prosthesis in the vessel). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the cover of Cox et al. to the stents in the manner taught by Brown et al. to minimize the cross-sectional area of the prosthesis.

7. Regarding claim 20, Examiner asserts the use of a specific knot would have been obvious to one of ordinary skill in the art at the time the invention was made and that by using any of the claimed knots, no unexpected results would be produced.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al. (2002/0120327) in view of Brown et al. (5,769,887) as applied to claim 17 above, and further in view of McNamara et al. (6,004,347). The combination of Cox et al. and Brown et al. does not disclose barbs extending from the stent through the graft. Attention is drawn to McNamara et al., who teach a graft disposed on the outside of a stent with a barb penetrating through the graft (see figures 10 and 11) to hold the graft onto the stent and to more securely anchor the stent against the vessel wall when deployed. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used barbs on the stents of the combination of Cox et al. and Brown et al. in the manner taught by McNamara et al. to hold the graft

Art Unit: 3731

onto the stent and to more securely anchor the stent against the vessel wall when deployed.

Response to Arguments

9. Applicant's arguments filed 18 December 2008 have been fully considered but they are not persuasive. Applicant argues the stent-graft of the prior art as set forth above would not be suitable for providing continuous pressure against the aorta lumen to seal off tear in the vessel. However, Examiner notes that this intended use is not claimed at any point in the pending claims. Further, even if this intended use were claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the **claimed** invention and the prior art in order to patentably distinguish the **claimed** invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

10. The arguments against the structural disclosure of Cox et al. have been addressed above.

11. Examiner also notes that even if the deficiencies of claim 1 are remedied, Brown et al. disclose multiple stents covered by a graft (the stents shown in phantom lines in figure 8) and also multiple stents that are uncovered (at 13). Therefore, Examiner wishes to make clear that if the deficiencies outlined above are remedied, the claims would not be in an allowable state in view of the art cited to Brown et al.

Conclusion

Art Unit: 3731

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731
27 February 2009

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731